IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Tsang et al. Art Unit: 1645

Application No. 10/072,722

Filed: February 5, 2002

For: COMPOSITIONS AND METHODS FOR DETECTING ADULT TAENIA SOLIUM

Examiner: Padma Baskar

Date: June 17, 2003

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

1. We, Victor C. W. Tsang, Ph.D., Patricia P. Wilkins, Ph.D. and James C. Allan, Ph.D. are co-inventors named in the above-referenced patent application, i.e. United States Application No. 10/072/722 (herein the '722 application).

2. We have read and understand the above-referenced patent application, including the pending claims, and the Office action dated March 25, 2003. We understand that the claims pending in the present application have been rejected in view of the Ko and Ng publication (J. Helminthology, 72:147-54, 1998). We understand that the Ko and Ng publication has been cited as allegedly anticipating (or rendering obvious) pending claims 1-7 and 21-25 of the above-referenced patent application.

3. The Ko and Ng publication published in June 1998. We, the inventors named on the '722 application, invented the subject matter of the claims pending in the '722 application prior to June 1998. This is evidenced by our publication of an abstract in December 1997 that disclosed that we were "developing a serologic assay using excretory/secretory (TS/ES) antigens of adult *T. solium* tapeworms to identify adult tapeworm carriers." (Wilkins *et al.*, Annual meeting of American Society of Tropical Medicine and Hygiene, Lake Buena Vista, FL (USA), December 7-11, 1997).

4. Accompanying this declaration as Exhibit A is a copy of the Wilkins *et al.* abstract, provided by Examiner Baskar. The abstract discloses three immunogenic *T. solium* excretory/secretory peptides (33 kDa, 38 kDa, and 42 kDa), that were isolated from *T. solium* adult worms. The abstract concludes that these isolated proteins can be used to diagnose *T. solium* tapeworm carriers.

5. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Victor Tsang, Ph.D.	Date
Patricia P. Wilkins, Ph.D.	6/19/2003 Date
James C. Allan, Ph.D.	Date

WDN:SLR:dm:dnr 06/17/03 198059.doc
PATENT

Attorney Reference Number 6395-62261
Application Number 10/072,722

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Patricia P. Wilkins, Ph.D.	Date
James C. Allan, Ph.D.	19 JUNE 03. Date

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2. We have read and understand the above-referenced patent application, including the pending claims, and the Office action dated March 25, 2003.

3. The invention disclosed in the above-referenced patent application has an important role in stopping transmission of taeniasis and cysticercosis, the adult and larval forms of *T. solium* infection, respectively. The adult-specific *T. solium* excretory/secretory polypeptides disclosed in the application allow one to distinguish between larval and adult infections, and identify those patients having an adult infection. Carriers of the adult worm may be asymptomatic yet continue to pass eggs in their feces, thus continuing the life cycle of *T. solium*. Identification of adult worm carriers allows those patients to be treated, thus stopping transmission of taeniasis and cysticercosis.

4. It is our understanding that in Paragraph 8 of the Office action of March 25, 2003, claims 1-7 and 21-25, which concerns compositions and kits that include a *T. solium*

excretory/secretory peptide, were rejected as anticipated by Wilkins *et al.* (Annual meeting of American Society of Tropical Medicine and Hygiene, Lake Buena Vista, FL (USA), December 7-11, 1997). That document discloses subject matter derived from the inventors. The other co-authors of the document (M. Acosta, M. Verastegui, H. H. Garcia, and R. H. Gilman) are not co-inventors of the subject matter claimed in the above-referenced application, and were merely involved in carrying out assignments and work under the supervision and direction of the inventors. The non-inventor co-authors were merely listed as co-authors of the document to receive credit for having collaborated in the research program under our direction.

5. It is our understanding that in Paragraph 9 of the Office action of March 25, 2003, claims 1 and 21-25, which concern compositions and kits that include a *T. solium* excretory/secretory peptide, were rejected as anticipated by McManus (*Papua New Guinea Med. J.* 38:287-94, 1995). That document discloses an assay that uses antigens obtained from *T. solium* cysts to detect cysticercosis, the larval form of *T. solium* infection. In contrast, our invention is directed to compositions that include *adult*-specific *excretory/secretory T. solium* antigens, *not cystic* antigens, which can be used to identify patients having the *adult* form of the disease. Cystic antigens are those obtained from a cyst homogenate. In contrast, excretory/secretory antigens are obtained by growing the whole worm in a media, allowing the worm to excrete/secrete antigens into the media, removing the whole worms, and collecting the antigens that were excreted/secreted into the media. Therefore, our *adult*-specific *excretory/secretory T. solium* antigens are not disclosed by the larval-specific cystic *T. solium* antigens disclosed in McManus.

6. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Victor Tsang

Victor Tsang, Ph.D.

June 18, 2003

Date

Patricia P. Wilkins, Ph.D.

Date

James C. Allan, Ph.D.

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